

REMARKS

Claims 1-2, 4-18, 20-23, 25, 27-37, 39, and 41 are pending and stand rejected. Applicants respectfully request reconsideration of the present application in view of the above amendments and following remarks.

Applicants thank Examiner Wolf for extending the courtesy of a telephone interview to Applicants' undersigned representative on June 28, 2010. At Interview, Applicant summarized the claimed invention and the cited art, with particular focus on the Malaviya reference. The Examiner suggested adding structural limitations to the claims. Applicant awaits the result of any further search the Examiner may conduct.

Amendments to the Claims

Applicants amend claims 1, 21, and 25 are amended to recite that the cell growth conduit flap comprises at least one channel. Support for these amendments can be found throughout the specification, for example at paragraph 0034 of the published application. No new matter is added.

Rejections Pursuant to 35 U.S.C. §112

Applicants thank the Examiner for the withdrawal of the rejection of claims 30-33 pursuant to 35 U.S.C. §112, second paragraph.

Rejections Pursuant to 35 U.S.C. §103

Malaviya

The Examiner rejects claims 1, 2, 4-18, and 30-33 pursuant to 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Publication No. 2003/0036797 of Malaviya et al. ("Malaviya"). Applicants respectfully disagree.

Claim 1 recites a biocompatible meniscal repair device that includes a biocompatible tissue repair scaffold and a cell growth conduit flap attached to the tissue repair scaffold. The cell growth conduit flap contacts a tibial surface, extends to the synovium, and comprises at least one channel configured to communicate biological materials to a tissue defect in the meniscus. Claim 1 also recites that the density of the cell growth conduit flap is in the range

of about 150 mg/cc to 350 mg/cc. Applicants submit that claim 1 distinguishes over and is not obvious in light of Malaviya and represents allowable subject matter.

Malaviya fails to teach or suggest, among other things, a cell growth conduit flap comprising at least one channel configured to communicate biological materials to a tissue defect in the meniscus. The Examiner argues that “Malaviya distinctly shows portions of the cover including the tabs shown in fig.41 that extend beyond the meniscus to the synovium. As these tabs are an extension of the flap, and are formed of the same material, they are capable of communicating biological materials to the tissue defect.” However, there is no teaching or suggestion in Malaviya that the tabs, or any other portions of Malaviya’s device, include at least one channel configured to communicate biological materials to a tissue defect in the meniscus.

Malaviya teaches only that the tabs are fastened to surrounding tissue. *See* Malaviya at paragraphs 0169-0170. There is no teaching or suggestion in Malaviya that the tabs are even capable of communicating biological materials to a tissue defect in the meniscus, much less that the tabs include at least one channel configured to communicate those biological materials.

In contrast, Applicants’ invention provides a cell growth conduit flap with material properties and a structure, i.e. at least one channel, that communicate biological materials to a tissue defect in the meniscus. *See, e.g.*, published application at paragraph 0034. Malaviya teaches that fluids are simply channeled through the open space between layers of the device and thus fails to teach a cell growth conduit flap that communicates biological materials.

Furthermore, Malaviya also fails to teach or suggest a cell growth conduit flap that contacts a tibial surface and extends to the synovium. The Examiner continues to argue that “the device of Malaviya is capable of contacting the tibial surface and extending to the synovium.” This is incorrect. According to the teachings of Malaviya, the covers 232, 234, which the Examiner argues form the claimed cell growth conduit flap, cannot extend to the synovium. Malaviya teaches that the “adjacent radially outer portion of the original meniscus” is retained and contacts the device. The retained radially outer portion of the original meniscus thus prevents the device from being positioned in a manner that would

allow the covers 232, 234 to extend to the synovium. Therefore, according to the teachings of Malaviya, the cell growth conduit flap would not be capable of extending to the synovium.

Moreover, even if the device could be positioned such that the covers 232, 234 extended to the synovium, in such a position the device would no longer “conform to the space into which it is inserted such that the surrounding tissue of the remaining meniscus is in contact with the device,” as taught by Malaviya. See Malaviya at Par. 0018. The Examiner now argues that “if the device of Malaviya were extended to the synovium, it could still be in contact with the side portions of the surrounding tissue of the remaining meniscus such that it does not go against the teachings of Malaviya.” The Examiner is incorrect. As previously discussed, Malaviya teaches that the outer portion of the meniscus is retained. In particular, Malaviya specifically teaches that the device is positioned “against the rim 18 left by the surgeon.” Malaviya at paragraph 0140. The “surrounding tissue” that Malaviya teaches would be in contact with the device is not merely the “side portions of the surrounding tissue,” as alleged by the Examiner. Instead, the “surrounding tissue” must include the rim 18, i.e., the retained radially outer portion of the original meniscus. Therefore, positioning the device of Malaviya such that the covers extended to the synovium would run contrary to the teachings of Malaviya. The modification proposed by the Examiner would therefore change the principle of operation of Malaviya. If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. MPEP 2143.01(VI); *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

Accordingly, independent claim 1 distinguishes over Malaviya and represents allowable subject matter. Claims 2, 4-18, and 30-33 likewise distinguish over Malaviya by virtue of their dependence on claim 1.

Malaviya in view of Vallee

The Examiner rejects claims 21, 25, and 27 pursuant to 35 U.S.C. §103(a) as being unpatentable over Malaviya in view of US Patent No. 4,952,404 of Vallee at al. (“Vallee”). Applicants respectfully disagree.

Claim 21 recites a method of surgically repairing meniscal defects that includes positioning a tissue repair scaffold in contact with a defect in a meniscus while positioning a

cell growth conduit flap in contact with a tibial surface and the synovium. The Examiner admits that “Malaviya does not specifically disclose the step of positioning a cell growth conduit flap in contact with the synovium.” The Examiner thus relies on Vallee to remedy the deficiencies of Malaviya. In this regard, the Examiner asserts that Vallee “teaches that it is known that meniscal tears may be healed if they communicate with the synovial membrane.” The Examiner then argues that it would have been obvious to one of ordinary skill in the art at the time of the invention to “modify the placement of Malaviya such that the covers contact the more vascularized synovium in order to promote healing of the meniscus as taught by Vallee.”

At the outset, Vallee merely discloses that “meniscus can be healed by connective tissue provided that the tear communicates with the synovial membrane laterally.” Vallee at col. 1, lines 17-19. There is no teaching or suggestion in Vallee regarding the placement of an implant. Moreover, the covers 232, 234 of Malaviya, which the Examiner argues form the claimed cell growth conduit flap, cannot be positioned in contact with a tibial surface and the synovium without disregarding the express teachings of Malaviya. As discussed in more detail above, Malaviya teaches that the “adjacent radially outer portion of the original meniscus” is retained and contacts the device. The retained radially outer portion of the original meniscus thus prevents the device from being positioned in a manner that would allow the covers 232, 234 to contact the synovium. Moreover, even if the device could be positioned such that the covers 232, 234 contact the synovium, in such a position the device would no longer “conform to the space into which it is inserted such that the surrounding tissue of the remaining meniscus is in contact with the device,” as taught by Malaviya. *See* Malaviya at paragraph 0018. Therefore, according to the teachings of Malaviya, the cell growth conduit flap would not be capable of extending to the synovium. The modification proposed by the Examiner would therefore change the principle of operation of Malaviya. If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. MPEP 2143.01(VI); *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). The Examiner therefore fails to present a *prima facie* case of obviousness with respect to claim 21.

Furthermore, claim 21 also recites that the cell growth conduit flap includes at least one channel configured to allow cells and nutrients to travel through the cell growth conduit flap to the defect in the meniscus. As discussed above, Malaviya teaches only that the tabs are fastened to surrounding tissue. *See* Malaviya at paragraphs 0169-0170. There is no teaching or suggestion in Malaviya that the tabs are even capable of allowing cells and nutrients to travel through the tabs, much less that the tabs include at least one channel configured to do so. Accordingly, claim 21, as well as claims 22-23 and 39, which depend therefrom, distinguish over Malaviya in view of Vallee and represent allowable subject matter.

Claim 25 recites a method of surgically repairing meniscal defects that includes positioning a cell growth conduit flap in contact with a tissue defect in a meniscus and in contact with a tibial surface and the synovium. Claim 25 also recites that the cell growth conduit flap includes at least one channel effective to allow cells and nutrients to travel through the cell growth conduit flap to the defect in the meniscus. Applicants' arguments with respect to claim 21, above, apply with equal force to claim 25. Accordingly, claim 25, as well as claims 27-29 and 41, which depend therefrom, distinguish over Malaviya in view of Vallee and represent allowable subject matter.

Malaviya in view of Vallee and Li

The Examiner rejects claims 22, 23, 28, and 29 pursuant to 35 U.S.C. §103(a) as being unpatentable over Malaviya in view of Vallee and further in view of US Patent No. 4,790,819 of Li et al. ("Li"). Applicants respectfully disagree.

First, Li fails to remedy the deficiencies of Malaviya in view of Vallee. Claims 22-23 and claims 28-29 depend from claims 21 and 25, respectively, and therefore distinguish over Malaviya in view of Vallee for all the reasons discussed above with respect to claims 21 and 25. The Examiner admits that Malaviya does not disclose the rasping step recited in claims 22 and 23. The Examiner relies on Li to teach the rasping step. Although Li teaches "using an arthroscopy rasp to abrade the superior and inferior parameniscal synovium," Li does not remedy the deficiencies of Malaviya in view of Vallee with respect to the features recited in claim 21 and 25 from which claims 22-23 and 28-29 depend. *See* Li at col. 1, lines 27-31.

Second, contrary to the Examiner's assertions, Li does not disclose rasping the meniscus in combination with placement of a fibrin clot material. Li discloses "a delivery device for depositing an exogenous fibrin clot into a wound site during an arthroscopic surgical operation." Li at Abstract. As discussed above, claims 21 and 25, as amended, recite positioning the cell growth conduit flap in contact with the synovium. In the background of the invention, Li discloses "using an arthroscopy rasp to abrade the superior and inferior parameniscal synovium to increase blood supply to the meniscal tear." (Li at Col. 1, lines 27-31). However, Li does not teach or suggest depositing the fibrin clot material in contact with the synovium. Li merely discloses injecting "a quantity of fibrin clot material into the meniscal tear within the wound site." (Li at Col. 6, lines 63-65). In addition, Li does not disclose using the rasping step in combination with depositing the fibrin clot material. Indeed, Li's invention represents an improvement to methods that require rasping the synovium to create a fibrin clot.

Regardless, Li fails to remedy the deficiencies of Malaviya in view of Vallee because Li fails to teach or suggest that the fibrin clot material is placed in contact with the synovium or a cell growth conduit flap including at least one channel. Claims 22, 23, 28, and 29 therefore distinguish over Malaviya in view of Vallee and Li and represent allowable subject matter.

Malaviya in view of Schwartz

The Examiner rejects claims 20 and 34-37 pursuant to 35 U.S.C. §103(a) as being unpatentable over Malaviya in view of US Patent No. 6,468,314 of Schwartz et al. ("Schwartz"). Applicants respectfully disagree.

At the outset, claims 20 and 34-37 ultimately depend from claim 1 and therefore distinguishes over Malaviya for all the reasons discussed above with respect to claim 1. Schwartz fails to remedy the deficiencies of Malaviya with respect to the claimed cell growth conduit flap including at least one channel configured to communicate biological materials to a tissue defect in the meniscus.

Moreover, one of ordinary skill in the art would not have modified the covers 232, 234 of Malaviya, which the Examiner argues form the claimed cell growth conduit flap, based on the void volume of the insert 16 disclosed by Schwartz. The insert 16 is contained

within a porous film 22 formed of bio-absorbable material. Schwartz at col. 9, lines 34-36. Thus, even if it would have been obvious to modify Malaviya in view of Schwartz, presumably one of ordinary skill in the art relying on Schwartz would have modified the mass of biological material 60 contained within the covers, not the covers themselves, to have the at least 95% voids by volume taught by Schwartz. Such a modification would clearly fail to teach or suggest the claimed void volume range of a cell growth conduit flap.

Accordingly, claims 20 and claims 34-37 distinguish over Malaviya in view of Schwartz and represents allowable subject matter.

Malaviya in view of Vallee and Schwartz

The Examiner rejects claims 39 and 41 pursuant to 35 U.S.C. §103(a) as being unpatentable over Malaviya in view of Vallee and further in view of Schwartz. Applicants respectfully disagree.

Claims 39 and 41 depend from claims 21 and 25, respectively, and therefore distinguish over Malaviya in view of Vallee for all the reasons discussed above with respect to claims 21 and 25.

Moreover, claims 39 and 41 each recite that the cell growth conduit flap has a void volume in the range of about 50% to 95%. However, as discussed above with respect to claim 20, one of ordinary skill in the art would not have modified the covers of Malaviya based on the void volume of the insert 16 disclosed by Schwartz. The insert 16 is contained within a porous film 22 formed of bio-absorbable material. Schwartz at col. 9, lines 34-36. Thus, even if it would have been obvious to modify Malaviya in view of Schwartz, presumably one of ordinary skill in the art relying on Schwartz would have modified the mass of biological material 60 contained within the covers, not the covers themselves, to have the at least 95% voids by volume taught by Schwartz. Such a modification would clearly fail to teach or suggest the claimed void volume range of a cell growth conduit flap.

Accordingly, claims 39 and 41 distinguish over Malaviya '797 in view of Vallee and Schwartz and represent allowable subject matter.

Conclusion

Applicants submit that all pending claims are allowable, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed necessary to expedite prosecution of this application.

Dated: July 19, 2010

Respectfully submitted,

By /George A. Xixis/
George A. Xixis
Registration No.: 38,664
NUTTER MCCLENNEN & FISH LLP
World Trade Center West
155 Seaport Boulevard
Boston, Massachusetts 02210-2604
(617)439-2746
(617) 310-9746 (FAX)
Attorney for Applicants

1936743.1